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Investigating cognitive training tasks to reduce heavy drinking

Submission date	Recruitment status	[ ] Prospectively registered
13/12/2018	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
18/01/2019	Completed	[X] Results
Last Edited	**Condition category**	[ ] Individual participant data
11/12/2019	Mental and Behavioural Disorders	

Plain English summary of protocol

Background and study aims
The study is designed to improve our understanding of aspects of cognitive functioning associated with alcohol consumption. The researchers plan to investigate how the brain responds to certain computerised cognitive tasks involving processing alcohol images. This research will help us understand processes that may be important in developing new ways to help people reduce their current alcohol consumption.

Who can participate?
People aged between 18 and 65 who drink more than 21 units per week and are interested in reducing their drinking

What does the study involve?
Participants complete a screening questionnaire to check whether they can take part in the main study. This include questions about their medical history and can be done online. The main appointment for this study involves:
1. Attending the University of Manchester and giving a breath test and urine sample to ensure no presence of drugs or alcohol that day. A minimum list of drugs that are screened for includes amphetamines, barbiturates, cocaine, opiates, cannabinoids and benzodiazepines. A positive result for one of these drugs would only exclude participants from taking part that day. After a single positive result, their appointment will be reschedule after allowing time for whichever drug screened positive to clear their system (this time will dependent on the substance in question). A second positive result at the rescheduled appointment would result in full study exclusion. All urine samples will be immediately destroyed after testing
2. Being asked about drug and alcohol use, as well as briefly about mental and physical health
3. Filling in some questionnaires to assess personality, alcohol use (in detail) and current mood
4. Doing some practice versions of the computer tasks that will be conducted within the MRI scanner. These provide information about how people react and think in particular ways
5. Walking with the researcher over to the Clinical Research Facility on Grafton Street to complete the full versions of these computer tasks within an MRI scanner that takes about one hour. Participants do each task twice, before and after some task-specific instructions

6. Undergoing a short structural scan within the MRI scanner
Four weeks after the main appointment, participants are contacted by the researcher by telephone or email to ask about alcohol consumption since the scan.

What are the possible benefits and risks of participating?
There were no direct benefits of taking part. There are indirect benefits of improving knowledge around alcohol use and potentially informing future research. The principal investigator will complete a detailed safety debriefing concerning the use of the MR scanner and standard safety procedures to be used by the clinical team will be adhered to. The only risks associated with MRI are for people with certain established contraindications, including heart pacemakers and metal surgical clips or implants in the head or neck. The CRF scanner has established safety procedures, including a detailed checklist that the radiographers go through with all participants prior to scanning. MRI scanning is generally well tolerated but some participants find the scanner environment claustrophobic and/or too noisy. Participants are provided with ear protection and a panic button which they can press to stop the scan at any time.

Where is the study run from?
The University of Manchester (UK)

When is the study starting and how long is it expected to run for?
July 2017 to December 2017

Who is funding the study?
Investigator PhD funded

Who is the main contact?
Elly McGrath

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
2017-0513-543

Study information

Scientific Title
Investigating cognitive training tasks to reduce heavy drinking: a randomised controlled trial

Study objectives
This study hypothesises that participants receiving implementation intentions will show reduced alcohol consumption, greater improvement on behavioural training task performance and increased activity in the medial frontal cortex and inferior frontal gyrus than control participants.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Manchester University REC, 27/03/2017, ref: 2017-0513-543

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Prevention

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet.

Health condition(s) or problem(s) studied
Heavy alcohol use

Interventions
Participants were randomised using the simple randomisation technique of a random number table. Participants attended the University of Manchester, and following consent, an alcohol

breath test and drug urine screen will be obtained. Demographic information was collected and an assessment of drug and alcohol history, including the SCID (Structured Clinical Interview for Depression) for dependence history, was conducted. A 28-day Timeline followback was be used to assess alcohol consumption. The 32 participants attended for a maximum 2 hour session comprising personality measures and neuropsychological testing both inside and outside of the scanner. Participants are randomised to read either an implementation intention or goal intention directed at task performance inside the scanner after the first round of neuropsychological tasks, but before repeating them. All questionnaires and tests were computerised and participants will perform the practice tests and questionnaires in a designated quiet testing room, with comfort breaks as required. The scanning element of the test session took approximately one hour. Questionnaire measures included measures of current alcohol behaviour, attitudes and habits as well as of impulsive behaviours. Participants were contacted one month later to complete another 28 day Timeline Followback via telephone.

Intervention Type
Behavioural

Primary outcome measure
Alcohol consumption measured using a 28-day Timeline Followback at baseline and one month follow-up

Secondary outcome measures
1. Cognition measured using reaction times and errors on the Approach Avoidance and Visual Probe tasks at a single session
2. Blood-oxygen-level dependent (BOLD) activity assessed using MR techniques at a single session

Overall study start date
01/07/2017

Completion date
01/12/2017

Eligibility

Key inclusion criteria
Consumption of 21 or more units of alcohol per week but not meeting SCID criteria for dependence

Participant type(s)
Healthy volunteer

Age group
Adult

Sex
Both

Target number of participants
32

Total final enrolment
32

Key exclusion criteria
1. Participants must not meet criteria for alcohol dependence as per the Structured Clinical Interview for Depression (SCID) (as assessed at online screening and during baseline interview)
2. Positive drug/alcohol screens on testing visits. A minimum list of drugs that will be screened for include amphetamines, barbiturates, cocaine, opiates, cannabinoids and benzodiazepines. Positive results for cannabinoids will be allowed given the long half-life of cannabinoid metabolites. This exclusion criterion would exclude a subject from completing the study on that day only and not the study as a whole, at the discretion of the research team
3. High dosage use of regular psychoactive prescription medications such as those with antidepressant or anxiolytic properties.
4. History or presence of a neurological diagnosis (not limited to but including, for example, stroke, epilepsy, space occupying lesions, multiple sclerosis, Parkinson's disease, vascular dementia, transient ischemic attack) that may influence the outcome of any cognitive testing
5. Clinically significant head injury (e.g., requiring medical or surgical intervention)
6. Unwillingness or inability to follow the procedures outlined in the protocol
7. Significant current or past psychiatric history, including Major Depression, Generalised Anxiety Disorders, or anything that involves referral to secondary services and/or significant functional impairment
8. Neuroendocrine disorder, including impaired thyroid function and steroid use
9. Female participants who are, or may be, pregnant
10. Those with any contraindications for MRI scanning will be excluded

Date of first enrolment
14/07/2017

Date of final enrolment
14/11/2017

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University of Manchester
Oxford Road
Manchester
United Kingdom
M13 9PT

Sponsor information

Organisation
University of Manchester

Sponsor details
Oxford Road
Manchester
England
United Kingdom
M139PT

Sponsor type
University/education

Website
www.manchester.ac.uk

ROR
https://ror.org/027m9bs27

Funder(s)

Funder type
Other

Funder Name
Investigator PhD funded

Results and Publications

Publication and dissemination plan
Intend to publish in a peer-reviewed journal in 2019.

Intention to publish date
31/12/2019

Individual participant data (IPD) sharing plan
Confidentiality: Each participant will be identified by an individual anonymised code number that will be used throughout the duration of the study. Participant names, addresses, and other contact details will be stored securely (in a locked filing cabinet) and kept completely separate from all their data. Only fully anonymised data will be stored on laptop computers which cannot be traced to individuals without study codes filed separately and only accessible to the research team. Computerised databases containing anonymised data will additionally be fully encrypted using
the high level encryption software recommended by the University of Manchester. Urine

samples will be identified by code number only and will be destroyed immediately after screening.
Unanonymised personal data will only be accessible to the study team. Additionally, study data and material may be looked at by individuals from the University of Manchester for essential monitoring and auditing purposes, and this may well include access to personal information. Consent forms will be retained as essential documents, but items such as contact details will be deleted as soon as they are no longer needed. The University of Manchester policy on storage of data is 5 years after the last publication of the study or for 10 years, whichever is the greater. Alcohol consumption change and cognitive tasks will be analysed using univariate and multivariate techniques from SPSS as appropriate. Imaging data will be analysed using multivariate techniques from SPM for MATLAB as appropriate.

IPD sharing plan summary
Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	25/05/2020	11/12/2019	Yes	No